



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,375	03/10/2005	Ute Heim	13173-00008-US	7304
23416 7590 10/02/2007 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899			EXAMINER PAGE, BRENT T	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 10/02/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/527,375

Applicant(s)

HEIM ET AL.

Examiner

Brent Page

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-16 and 18-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 03/10/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of SEQ ID NO:1 in the reply filed on 06/20/2007 is acknowledged. The traversal is on the ground(s) that Conrad et al does not anticipate the special technical feature which is urged by Applicants to be a selective sink storage tissue promotore. This is not found persuasive because the claims do not specify that expression is specific to sink tissue but rather that expression occurs in sink tissue. A seed-specific promoter would direct expression in a sink tissue and essentially not in source tissues and therefore Conrad et al do anticipate the technical feature, rendering it non-special.

The requirement is still deemed proper and is therefore made FINAL.

Claim 6 is withdrawn as it is drawn to nonelected subject matter.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-16 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1, does not reasonably provide enablement for all promoter sequences that comprise "at least one promoter sequence" of the gene encoding *Vicia faba* plastidic 1,4-alpha-D-glucan:phosphate alpha-D-glucosyltransferase wherein one promoter sequence could be considered to be as little as 2 base pairs of that particular sequence or merely the TATAA box. The

Art Unit: 1638

specification also does not reasonably provide enablement for all promoter effective sequences that share at least 40% homology with at least 100 base pairs of SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for the directed, transgenic expression of nucleic acid sequences in carbohydrate-storing sink tissues of plants, which comprises introducing into the plant cells, a transgenic expression cassette comprising at least one promoter sequence of the gene encoding the *Vicia faba* plastidic 1,4-alpha-D-glucan:phosphate alpha-D-glucosyltransferase, wherein the promoter sequence could be as little as two nucleotides of the promoter from said gene as part of a different promoter, and an isolated nucleic acid, a transgenic expression cassette, a transgenic organism and a cell culture all from the method recited above.

In contrast, the specification only provides guidance for the sequence of SEQ ID NO: 1, the smallest fragment disclosed, as functioning as a promoter (1300 base pairs) and does not provide any guidance for any smaller fragments, or any embodiments of sequences containing substitutions, deletions or derivatives that would also function as promoters in the claimed invention.

The function of promoter fragments and sequence variants in transgenic plants is unpredictable. Kim et al (1994, *Plant Molecular Biology* 24:105-117) in a mutational analysis of the nopaline synthase promoter in a stable transformation system, found that mutation of a single nucleotide significantly altered the strength of expression, while

Art Unit: 1638

deletions in other regions of the promoter completely eliminated function (page 108 first full paragraph).

Deletion analysis of promoters is unpredictable. Donald et al (1990, EMBO J. 9:1717-1726) teach that a crucial promoter element for the *Arabidopsis* rcbS-1A promoter is located in the region about 250 bases upstream of the transcription initiation site.

Furthermore, the function of promoter fragments and sequence variants in transgenic plants is unpredictable wherein the promoter function is regulated by conditional elements. Dolferus et al (1994, Plant Physiology 105:1075-1087) in a deletion analysis of the *Arabidopsis* Adh promoter, found that deletion of different elements of the promoter affected promoter function conditional to the stress that was applied to the given promoter fragment (page 1080, last full paragraph and page 1082 first full paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate all promoter-effective molecules from the *Vicia faba* plastidic 1,4-alpha-D-glucan:phosphate alpha-D-glucosyltransferase gene as broadly claimed.

Claims 1-5, 7-16 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1638

The claims are broadly drawn to a multitude of sequences that would function as a tissue specific promoter, wherein literally millions of embodiments are claimed having as little as 40% homology to as little as 100 base pairs of SEQ ID NO: 1, and further, wherein a "promoter sequence of the *Vicia faba* plastidic 1,4-alpha-D-glucan:phosphate alpha-D-glucosyltransferase gene" is claimed, wherein any sequence from the identified promoter would meet this limitation and comprising millions of embodiments that would be non-functional.

In contrast, the specification only describes the sequence of SEQ ID NO: 1, the smallest fragment disclosed, as functioning as a promoter (1300 base pairs) and does not provide the description of any smaller fragments, or any embodiments of sequences containing substitutions, deletions or derivatives that would also function as promoters in the claimed invention.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed

Art Unit: 1638

genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in

Art Unit: 1638

possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Barry et al (US Patent 6235971).

The claims are broadly drawn to a method for the directed, transgenic expression of nucleic acid sequences in carbohydrate-storing sink tissues of plants, which comprises introducing into the plant cells, a transgenic expression cassette comprising at least one promoter sequence of the gene encoding the *Vicia faba* plastidic 1,4-alpha-D-glucan:phosphate alpha-D-glucosyltransferase, wherein the promoter sequence could be as little as two nucleotides of the promoter from said gene as part of a different promoter and a transgenic expression cassette comprising said at least one promoter sequence wherein the transgenic expression cassette comprises at least one or more genetic control elements.

Barry et al teach the expression of sucrose phosphorylase in the carbohydrate sink-storing tissues of plants wherein the gene is heterologously and functionally linked



Art Unit: 1638

to the class I patatin promoter that comprises the TATAA box at the very least which is inherently a promoter sequence from the gene encoding the *Vicia faba* plastidic 1,4-alpha-D-glucan:phosphate alpha-D-glucosyltransferase and further comprising targeting signal sequences (see Column 4, lines 48-61, Column 6, lines 61-64, for example and claim 1 and claim 22, for example).

Claims 2-5 and 8-16 are free of the prior art, given the failure of the prior art to teach or reasonably suggest the targeted expression of nucleic acid sequence comprising transforming a plant with SEQ ID NO:1, or a nucleic acid sequence having at least 40% homology to at least 100 nucleotides of SEQ ID NO:1 wherein the sequence is heterologously and functionally linked to an additional nucleic acid sequence wherein the expression of the sequence is in sink tissues or the isolated sequence of SEQ ID NO:1.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (571)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

RUSSELL P. KALLIS, PH.D.  
PRIMARY EXAMINER

*Russell Kallis*